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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/069,481 | 02/27/2002 | Hiroaki Takayama | TAKAYAMA10 | 3430 |

1444 7590 09/10/2002

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| EXAMINER |
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QAZI, SABIHA NAIM

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| ART UNIT | PAPER NUMBER |
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1616

DATE MAILED: 09/10/2002 *H*

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,481

Applicant(s)

TAKAYAMA ET AL.

Examiner

Sabiha Naim Qazi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 25 August 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1616

First Office Action on Merits

Invention: *The instant invention is drawn to 2-substituted vitamin D₃ derivative, their composition and method of use.*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Status of the Application

Claims 1-15 are pending and rejected.

No claim is allowed. Preliminary amendments are entered.

Priority

If applicant desires priority, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph.

Information Disclosure Statement

No information disclosure statement filed. International Search Report filed has been placed in the application file; if applicant wants to publish the cited references on the face of the patent they must file an IDS.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

1. Claims 1-12 rejected under 35 U.S.C. 102(b) as being anticipated by Mayamoto et al. '168, see examples 1-5, 8 and 11-16.
2. Claims 1-15 rejected under 35 U.S.C. 102(b) as being anticipated by Posner et al. (WO 96/01811). See compounds 2 and 3 on page 4.
3. Claims 1-15 rejected under 35 U.S.C. 102(b) as being anticipated by Ono et al. (Chem. Pharm. Bull). See compounds 10, 11, 12, 16, 17, 26 and 27 on page 1627 of the reference.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

1. Claim 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyamoto et al. (US Patent 5,877,168). Miyamoto et al. teach vitamin D derivatives with substituents at 2b-position, which embraces instantly claimed invention. See the entire document especially formula (I) in col. 2 and lines 33-42, where R_1 represents hydrogen or a hydroxy group and R_2 represents straight chain or branched lower alkyl group having 1-7 carbon atoms has been taught.

The instant claims differ from the reference in being broader in generic scope. Prior art teaches at 2-position alkyl, alkenyl and alkynyl groups wherein instant invention is claiming aliphatic saturated hydrocarbon. A disclaimer in claim 1 for methyl at 2-position is noted.

One having ordinary skill in the art would be motivated to prepare additional derivatives of vitamin D_3 because prior art teaches 2-substituted vitamin D derivatives for various uses. The compounds of Miyamoto et al. are known to have in vitro calcium regulatory activity and differentiation stimulating activity on tumor cells, etc. and are useful as treating agent for diseases caused by abnormal calcium, such as osteoporosis and osteomalacia, or as an antitumor agent. See col. 1, lines 10-19.

It would have been obvious who is even familiar with the art at the time of invention to prepare the compounds and compositions for various uses as instantly claimed.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Art Unit: 1616

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Naim Qazi whose telephone number is 703-305-3910. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

August 30, 2002



SABIHA QAZI, PH.D
PRIMARY EXAMINER